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COLLARD & ROE, P.C.
1077 NORTHERN BOULEVARD
ROSLYN, NY 11576

EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	**PAPER NUMBER**
3763	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,928	EICHHORST, PETER	
	Examiner	Art Unit	
	Quynh-Nhu H. Vu	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20 and 22-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20, 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Amendment filed on 12/10/07 has been entered.

Claims 1-20, 22-25 are present for examination.

Claim 21 is cancelled.

Applicant's arguments filed on 12/10/07 have been fully considered but are not persuasive. Therefore, claims 1-25 are rejected in the same ground rejections as set forth in the office action mailed 12/10/07.

The claim rejections under 35 USC §112, 1st and 2nd paragraph have been withdrawn in view of amendments filed on 12/10/07.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1- 20, 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Neracher (WO 02/49697).

Neracher discloses, in Figs. 1-2, an injection device for needle-free injection of a medium into the tissue of a human or an animal wherein a needle-free pre-injection device 3, and a main injection device.

Regarding claim 2, the pre-injection device has a first chamber 2 and the main injection device has a second chamber 13 or 7; a nozzle 20 intended to be set onto the skin is connected with the chamber 2 of the pre-injection device and with the outlet of the main injection device by way of a kick-back valve 14, 15; and a pressure-production device 5 or 8 or 206 that is connected with the chamber 2 of the pre-injection device is configured to produce a high-pressure jet from the nozzle 20 that penetrates

the tissue, whereby the chamber 2 of the pre-injection device has a volume sized exclusively for producing an injection channel in the tissue, and the chamber 7 of the main injection device has a volume intended for the medium to be injected.

Regarding claim 3, the chamber 7 of the main injection device has a piston 9 that can be moved by hand.

Regarding claim 5, the pre-injection device has a coupling device 237 for a connection with a main injection device that contains the medium to be injected.

Regarding claim 6, the pressure-producing device 5 or 6 or 206 or the pre-injection device has a pressure plate 11 or 234 or 239 biased by a spring force 238.

Regarding claim 7, a channel 205 connected with the nozzle 20 of the pre-injection device.

Regarding claim 8, a valve 14 or 15 is disposed within the channel (see Fig. 1a below).

Regarding claims 9-10, a trigger 16 holds a pressure plate 11 biased by a spring (see Fig. 1a below); or a trigger 239 holds a pressure plate 234 biased by a spring 238 (see Fig. 2b below); and a trigger is connected with the chamber 2.

Regarding claim 11, a membrane 21 (Fig. 1) or (a distal part of 210) is part of the piston 210 connected with chamber 2, and this membrane activates the trigger by way of a pusher 235 or 10 (Fig. 1).

Regarding claim 12, the channel 4 has a connection with the chamber 13, and the valve 14 or 15 is disposed between the connection and the coupling device (Fig. 1a)

Regarding claim 13, the chamber 4 has a piston 9 or 10 that rests against the pressure plate (Fig. 1a).

Regarding claim 14, the main injection device and pre-injection device have a common nozzle 20.

Regarding claim 15, a trigger 16 or 239 of the pre-injection device indirectly activated by the pressure produced by the main injection device.

Regarding claim 16, the pre-injection device and the main injection device have a common chamber 4 or 204 for accommodating the medium to be injected; a common pressure- production device 5 or 206.

Regarding claims 17-18, the common pressure production device 5 or 206 has a single spring (located at the valve 14, 15 of Fig. 1a) or 238, 245 of Fig. 2a; the common pressure production device has a means for reducing the size of a first, slight part of chamber in a first step, by a small volume, at a great pressure, and in a second step, by a great volume, at a low pressure (see page 14, line 14- page 15, line 7). Two springs 245 or 7 (act like spring).

Regarding claims 19-20, the pre-injection medium is a physiologically non-problematic liquid.

Regarding claims 21-24, they encompass the same scope of the invention as to that of claims above except they are drafted in method format instead of apparatus format. The claim(s) are therefore rejected for the same reason as set forth above. Also, see page 14, line 14-page 15, line 7 for more details)

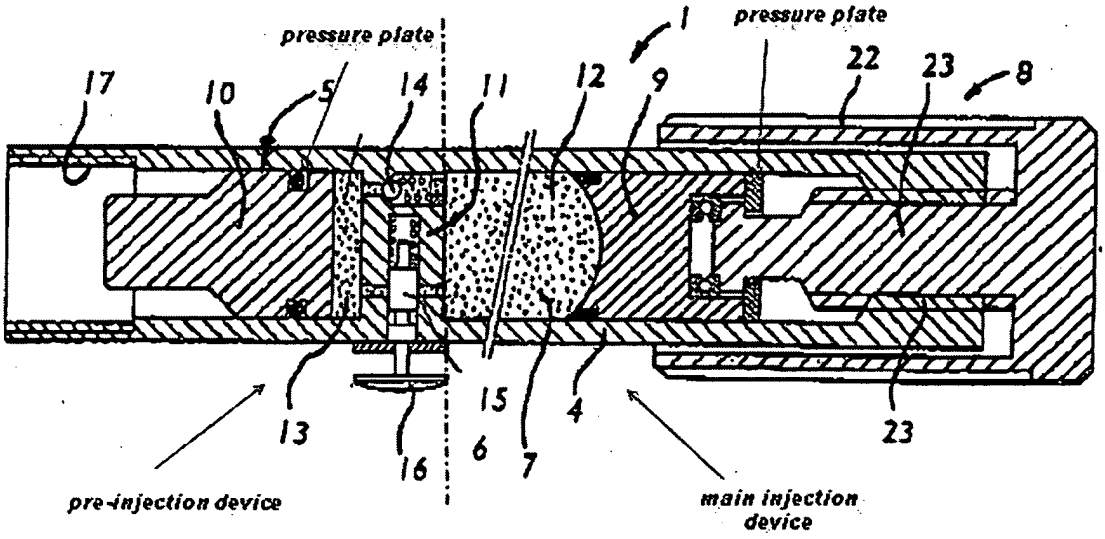
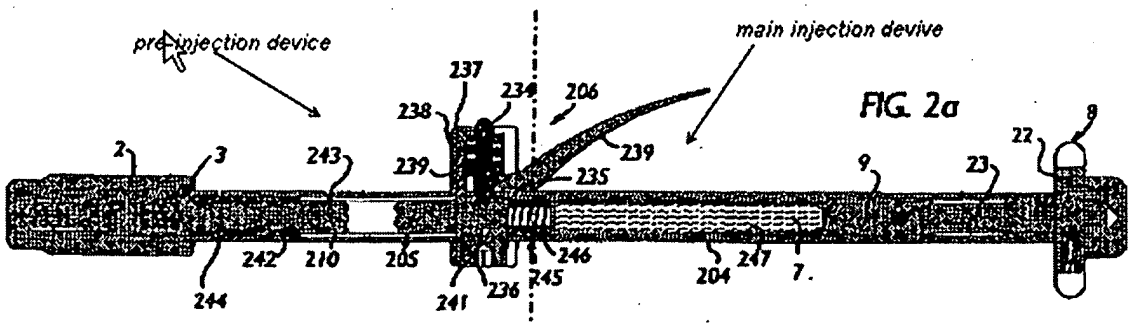


Fig. 1a



Claims 1 and 13-14, 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Dixon (US 4,722,728).

Regarding claims 1, 13-14, Dixon discloses a device for needle-free injection comprising a needle-free pre-injection device (part A), and a main injection device (part B) having a chamber B; wherein the chamber B has a piston 47 that rest against the pressure plate 21 and can be displaced in length, and a channel 44 is guided through the piston 47 and the pressure plate 21. The device has a common nozzle.

Regarding claims 17-18, Dixon discloses a damping means 18; a common pressure production device has springs 23 and 17 (Figs. 1-2) having different spring stiffness values and spring paths, whereby a first spring element 23 for moving the piston has a high spring stiffness and a short spring path, a second spring 17 has a low spring stiffness and a long spring path.

Response to Arguments

Applicant's arguments filed 12/10/07 have been fully considered but they are not persuasive.

1) Applicant argues that Neracher fails to disclose or suggest an injection device for needle-free injection including a pre-injection and a main injection device.

In response to applicant's arguments, the recitations "for needle-free injection" or "for production of a high-pressure jet of a pre-injection medium for producing an injection channel by means of a high

pressure and a small volume"..."for introduction of the medium to be injected" of claim 1 with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex Pane Masham, 2 USPQ F. 2d 1647 (1987). If the prior art structure is capable of performing the intended use, then it meets the claim. Beside that, a label, statement of intended use, or functional language do not structurally distinguish claims over prior art, which can function in the same manner, be labeled in the same manner or be used in the same manner. See In re Pearson, Ex parte Minks, and In re Swinehart.

2) Applicant argues that Neracher does not disclosure or suggestion of Applicant's device or method, which uses two steps injection procedure using a pre and a main injection device.

In response, Neracher discloses all claimed structure in above rejections. However, these steps must be performed in order to obtain the device. Therefore, the method of using would be inherent to the shown structure of the device. If Applicant still disagrees with Examiner that the needle-free device and a method for needle–free are distinguish from each others. In other words, the lists of method for needle-free injection are different from the device. The Applicant should withdraw or cancel either device or method claims. Otherwise, there is another Restriction/Election will happening in the next Office Action.

Similarly with response to above, A label, statement of intended use, or functional language do not structurally distinguish claims over prior art, which can function in the same manner, be labeled in the same manner or be used in the same manner. See In re Pearson, Ex parte Minks, and In re Swinehart.

Additionaly, Neracher discloses in Fig. 2f, the injection pressure is at high pressure at the injection start and low-pressure and injection time. See page 15, line 9+.

3) Applicant argues that the inject-able liquid 2 does not pass one of these valves.

In response, Neracher clearly discloses that a rotatable valve provided with a passage there through that interconnects the liquids container portion with the outlet nozzle orifice in an actuated position (see page 5, lines 28-30). Furthermore, it is very well-known in the art to provide with a kick-back valve that connected with the chamber of injection device.

4) Applicant argues that the reference number 237 of Neracher can not be used as a coupling device.

In response, the element 237 is coupling to pre-injection device. Furthermore, not only element 237 coupling to the pre-injection device, but or element 16 (Fig. 1a) or element 239 (Fig. 2) can be called coupling device.

5) Applicant argues that Neracher does not disclose a channel connected with the nozzle as claim 7.

In response, the element 17 of Fig. 1; or the elements 3 or 205 of Fig. 2 can be called a channel and connected with the nozzle.

6) Applicant argues that Neracher does not use any spring in claims 9-10.

In response, please see the rejection above.

7) Applicant argues that Neracher does not contain a pre-injection device and a main injection device.

In response, please see the Figs above that Examiner includes in the Office Action. The dotted line is d ivided between the pre-injection device and main injection device.

8) Applicant argues that Dixon no disclosure or suggestion of a device or method that uses a pre- and a main injection device for injection two different media so that the pre-injection device can be used instead of a needle in combination with, for example, normal syringes.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., for injection two different media so that the pre-injection device can be used instead of a needle in combination with, for example, normal syringes) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, the recitations "for injection two different media so that the pre-injection device can be used instead of a needle in combination with, for example, normal syringes) "for needle-free injection" or "for production of a high-pressure jet of a pre-injection medium for producing an injection channel by

means of a high pressure and a small volume"..."for introduction of the medium to be injected" of claim 1 with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex Pane Masham, 2 USPQ F. 2d 1647 (1987). If the prior art structure is capable of performing the intended use, then it meets the claim.

9) In conclusion, Applicant explains the difference between the applicant's invention and the device of Neracher. However, because the Applicant claims very broadly, the device structure of Neracher is able to read all claimed invention. If Applicant wants to over come the prior arts of Neracher and Dixon, Applicant must claim the structure more detail.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Quynh-Nhu H. Vu
Examiner
Art Unit 3763

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SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700